UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs,

-v-

MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC., and UDL LABORATORIES, INC.,

Defendants.

03 CIV. 8253 (DLC)

OPINION & ORDER

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs,

-v-

RANBAXY LABORATORIES, LTD., and RANBAXY PHARMACEUTICALS, INC.,

Defendants.

03 CIV. 8250

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs,

-v-

WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., WATSON PHARMA, INC., and DANBURY PHARMACAL, INC.,

Defendants.

03 CIV. 8254

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs,

-v-

ALPHAPHARM PTY. LTD. and GENPHARM,

04 CIV. 1966

INC., :
:
Defendants. :
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Appearances:

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DENISE COTE, District Judge:

Alphapharm Pty. Ltd., and Genpharm, Inc. ("Alphapharm") have moved in limine to exclude portions of the direct testimony from experts for Takeda Chemical Industries, Ltd., and Takeda Pharmaceuticals North America, Inc. ("Takeda"). The direct testimony for this bench trial was submitted in advance of trial through affidavits. This Memorandum Opinion and Order addresses the motions as to Takeda experts James Hendrickson ("Hendrickson"), Bruce Stoner ("Stoner"), and Loren Koller ("Koller").

Background

In 2004, Alphapharm sent Takeda notice that it had filed an Abbreviated New Drug application to market a generic version of Takeda's drug pioglitazone, marketed under the commercial name

ACTOS®, and that Alphapharm had certified in its application that the patents protecting pioglitazone were invalid or unenforceable. Alphapharm specifically claims that the '777 Patent, which protects the chemical compound for pioglitazone, is invalid due to obviousness. On March 12, 2004, Takeda brought suit against Alphapharm for infringement of the '777 Patent.

Hendrickson

Alphapharm seeks to exclude Hendrickson's testimony at paragraphs 64 to 72 of his affidavit, a section that addresses the selection of a lead compound for pharmacological development based on the disclosures in the prior art to the '777 patent. Hendrickson is an expert chemist who has performed extensive and sophisticated work in the field of synthesizing compounds, including for development as pharmaceuticals. Alphapharm argues that Hendrickson is not qualified through training or experience, however, to opine on selection of a lead compound. A lead compound is a compound chosen as a focal point for further research and modification in the process of creating a compound suitable for development as a pharmaceutical. In connection with this portion of the litigation, the parties principally dispute whether an article in a scientific journal, the Sodha II article, should be understood to identify "compound 58" in the article as a lead compound. At his deposition Hendrickson admitted that he had never been involved in making decisions about the selection of a lead compound. Hendrickson also concedes that he has no experience with toxicology.

The difference between (a) searching for an efficient path

to reach a known, or to create a new, compound and (b) choosing a starting point to search for a new compound, is significant. Alphapharm's motion to strike is granted to the extent that Hendrickson's affidavit seeks to opine on the selection of "compound 58" as a lead compound. To the extent that Hendrickson discusses other issues within his field of expertise within paragraphs 64 to 72, however, the motion is denied. For instance, Hendrickson sets out the structure of a certain TZD molecule, and calculates the number of compounds discussed in Sodha II that share certain chemical structures. These descriptions and classifications fall firmly within his field of expertise.

Stoner

Alphapharm has moved to limit the expert testimony of Stoner. For the reasons expressed in a companion opinion issued on January 9, 2006, in connection with a motion in limine brought by Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc., and UDL Laboratories, Inc. ("Mylan") to strike Stoner's evidence regarding Mylan's inequitable conduct claims, Alphapharm's motion is denied. To the extent that Stoner's testimony offers conclusions of law or opines on issues beyond his area of expertise, his testimony will be disregarded.

Koller

Alphapharm moves to preclude the testimony of Koller on the grounds that his testimony is speculative, that he is too skilled in the art to give an opinion for a person of ordinary skill, and

that his opinions are contradictory. The motion is denied.

Koller is an expert on toxicology and animal testing. Alphapharm argues that Koller's commentary about the meaning of various disclosures in the prior art to the '777 patent, specifically the Cunningham and Sodha II articles, are speculative and without support in the scientific literature. Alphapharm notes that Koller has not independently assessed the statements in the articles on which he relies. All of the statements on which Koller comments relate to issues of animal testing and toxicology. Koller was an expert in the field at the time the articles in question were published and remains an expert in the field today. Koller's testimony is not offered to verify the statements in the article, but to offer his expert opinion on how the articles would have been understood at the time. This is an entirely appropriate subject for testimony from this expert.

The remaining objections may be swiftly rejected. To the extent that Alphapharm argues that Koller is too expert to give a relevant opinion, Alphapharm may press that argument at trial. It is noteworthy in this regard that many of the opinions that Koller expresses are echoed by the defendants' own experts. As for asserted contradictions, Alphapharm has either distorted the record or over-simplified statements about complex issues.

Koller Supplemental Declaration

Alphapharm moves to strike Koller's December 8, 2005, supplemental declaration ("Supplemantal Declaration"), pursuant to Rule 37 of the Federal Rules of Civil Procedure, for unfair

surprise. The Supplemental Declaration was served to respond to Alphapharm's Proposed Findings of Fact of November 18, 2005, which asserted new grounds to attack the '777 patent as obvious. A brief history is in order.

Gerard Colca ("Colca") and Douglas Morton ("Morton") were first disclosed as witnesses by Takeda on September 30, 2005, subsequent to the close of fact discovery on May 27, 2005. Colca and Morton are fact witnesses whose testimony addresses the collaboration of Takeda with Upjohn Pharmaceuticals, Inc., and is being offered in defense of the '777 Patent against the claims of inequitable conduct raised by defendant Mylan in a related action, Takeda Pharmaceutical Industries, Ltd. v. Mylan Laboratories Inc., 03cv8253 (DLC).[1] Mylan moved to have their testimony precluded for Takeda's failure to disclose them in a timely manner by letter on October 18, 2005. Mylan's motion was denied, by Order dated October 21, 2005, to the extent their testimony addressed Mylan's inequitable conduct claims.

On Novemeber 18, 2005, the parties to the litigation submitted proposed findings of fact and conclusions of law, memorandum of law, affidavits or declarations, and exhibits. Included in Takeda's filings was a declaration from Koller. In its Proposed Findings of Fact, Alphapharm for the first time contended that the data on toxicity presented to the PTO during the prosecution of '777 patent was "inconsistent, unreliable and could not be replicated." Alphapharm, Proposed Findings of Fact,

[1] The two actions have been consolidated for trial purposes along with actions initiated by Takeda against two other generic drug manufacturers who have filed Abbreviated New Drug applications.

¶ 46.[2] Alphapharm based its assertion on documents produced by Takeda relating to Colca and Morton and on statements from their deposition testimony given in November 2005.

The Supplemental Declaration directly addresses the issues of toxicology and toxicity raised by Alphapharm in its Proposed Findings of Fact. It corrects errors of fact in Alphapharm's Proposed Findings of Fact and explains why the conclusions that Alphapharm seeks the Court to draw from comparisons of results from 2-week, 13-week, and one year toxicity tests are invalid.

Fairness dictates that Takeda be given an adequate opportunity to respond to the issues first raised by Alphapharm in its Proposed Findings of Fact. Takeda was given no notice through expert reports or discovery requests that Alphapharm intended to contest the toxicity data presented to the PTO. There was no opportunity to serve a timely expert report addressing Alphapharm's allegations because it had no notice of them until they were disclosed on Novemeber 18. The Supplemental Declaration is narrowly focused and addresses only those issues of toxicology put into question by Alphapharm. It will be of assistance to the Court to have expert testimony addressing the new issues raised by Alphapharm.[3]

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[2] The relevance of Alphapharm's assertions about the reliability of toxicity data to its claim that the '777 patent is invalid due to obviousness is tenuous at best. Alphapharm acknowledges in its Proposed Finding of Fact that the data on which it bases its position only became available in 1992, five years after the '777 Patent issued.

[3] Indeed, it is questionable whether there could be any reliable fact finding about the matters raised by Alphapharm without expert explication. It is noteworthy that Alphapharm has not sought to proffer any expert testimony to support its theory. It could, of course, have argued that the depositions of Colca and Morton in November 2005 entitled it to file late expert reports or present a new expert affidavit, but Alphapharm did not

Alphapharm's motion to strike the Supplemental Declaration is denied. Alphapharm's request to conduct a deposition of Koller on the issues raised in the Supplemental Declaration is granted. It may conduct a deposition of one hour in length. Its application for fees and costs is denied.

Conclusion

Alphapharm's motions in limine are granted in part. Alphapharm's motion to limit the testimony of Takeda expert Hendrickson is granted in part. Takeda shall serve a revised affidavit for Hendrickson to comply with the rulings in this Opinion by Friday, January 13 at 5:00 p.m. The parties shall confer regarding the proposed revisions and present any continuing disputes to the Court before the beginning of trial on January 17.

Alphapharm's motions to strike the testimony of Koller and Stoner are denied. Alphapharm's motion to strike the supplemental declaration of Koller is denied. Its request to conduct a deposition of Koller is granted, but that deposition shall be limited to one hour. Its application for fees and costs is denied.

SO ORDERED:

Dated: New York, New York
January 11, 2006

DENISE COTE
United States District Judge

make any such application.